510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

JUN 2 5 2013

NAME OF FIRM:
I.T.S. GmbH
Autal 28
Lassnitzhöehe A – 8301
AUSTRIA

510(k) FIRM CONTACT:
Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372
Tel. No. 952-492-5858
e-mail: allippincott@msn.com

DATE: December 20, 2012

TRADE NAME: **I.T.S. Ulna Locking Plates - (DUL & UOL) Systems**

COMMON NAME: Bone Plate System

CLASSIFICATION: Plate, Fixation, Bone &

Smooth or threaded metallic bone fixation appliances and accessories.

(see 21 CRF, Sec. 888.3030 & Sec. 888.3040).

DEVICE PRODUCT CODE: **HRS**

SUBSEQUENT PRODUCT CODE: **HWC**

SUBSTANTIALLY EQUIVALENT DEVICES
Medartis AG – APTUS Ulna Plates **(K103332)**
Zimmer – Periarticular Ulna Plate Systems **(K082078)**
Acumed - Congruent System Acu-Loc 2 Plate **(K120903 & K071715)**
TriMed - Ulnar Osteotomy Plate **(K043263)**
Synthes - 2.7mm LCP Ulna Osteotomy System **(K113364)**
OrthoPro - DC Ulnar Shortening System **(K073228)**
I.T.S. GmbH - Straight Plate w/Angular Stability **(K060156)**

DEVICE DESCRIPTION: The I.T.S. Ulna Locking Plates are composed of the DUL (Distal Ulna Locking) & UOL (Ulna Osteotomy Locking) Systems which are fracture fixation plating systems for repairing bone factures located in the distal and mid-ulna bone in the human body. The DUL System consist of three(3) Standard plate lengths of 3, 4, & 6 hole and one(1) Small pre-contoured plate shape in a left/right configuration to fit the distal ulna.

DEVICE DESCRIPTION Continued:

The UOL System consists of a single, 5 hole, straight plate for mid-ulna bone osteotomy procedures. Both plate systems are manufactured from Commercialy Pure (CP) Titanium material to allow for minor intra-operative forming/contouring by the surgeon. The plate design concept offers various type locking screw fixed-angle constructs using angular stability locking screws into the plate. Both locking and non-locking high strength 6-4 Alloyed Titanium screws in sizes of 2.4mm cortex locking, 2.7mm cortical non-locking, and 3.0mm cancellous/ cortical locking screws are offered. All screws are self-tapping for insertion into bone. Small holes in the plate allow intermediate 'k-wire' bone fracture segment positioning for reducing and aligning the fracture bone segments while positioning the plate and introduction of multiple sizes of locking/non-locking screws as needed for stabilizing the fracture – when using x-ray fluroscopy.

All I.T.S. Ulna Locking Plates and Screws are processed with an anodize 'DOTIZE' surface treatment. The low-profile and contoured plate design minimizes soft-tissue irritation for the patient. A full compliment of instrumentation is available for use with the system.

INTENDED USE:

The ***indications for Use*** of the I.T.S. GmbH Distal Ulna Locking (DUL) and Ulna Osteotomy Locking (UOL) Plate Systems is to stabilize fractures/osteotomy in the long bone of the distal and mid ulna of an adult patient.

The I.T.S. GmbH Ulna Locking Plate (DUL & UOL) Systems are not intended for spinal use.

EQUIVALENCE:

The I.T.S. GmbH Ulna Locking Plate DUL & UOL Systems are substantially equivalent to the Medartis AG, Zimmer, Acumed, TriMed, Synthes, OrthoPro, and I.T.S. GmbH bone plate systems. No nonclinical testing was used in the determination of substantial equivalence.

SUMMARY OF TECH-NOLOGICAL CHAR-ACTERISTICS

The I.T.S. GmbH Ulna Locking Plate DUL & UOL Systems are Similar in Material, Geometry Design/Markings, and Indications to predicate system(s) currently sold in the U.S. market.

SUMMARY OF SAFETY AND EFFECTIVENESS:

The I.T.S. GmbH Ulna Locking Plate DUL & UOL Systems are shown to be safe and effective for use in fracture fixation of long bones in the distal and mid-shaft areas of the ulna bone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 25, 2013

I.T.S. GmbH
% Engineering Consulting Service, Incorporated
Mr. Al Lippincott
U.S. Agent and Official Correspondent
3150 East 200th Street
Prior Lake, Minnesota 55372

Re: K130008
Trade/Device Name: I.T.S. Ulna Locking Plate (DUL/UOL) Systems
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: May 2, 2013
Received: May 22, 2013

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin D Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) NUMBER: _____

DEVICE NAME: **I.T.S. Ulna Locking Plate (DUL/UOL) Systems**

INDICATIONS FOR USE:

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The I.T.S. GmbH – Ulna Locking Plate (DUL & UOL) Systems are not intended for spinal use.

Prescription Use XXXX AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices